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OCT 23 2001

510(k) Summary
for
Meridian Medical Technologies Ltd
TelePress III Blood Pressure Monitor

Submitter	Meridian Medical Technologies Ltd 207 Airport Road West, Belfast BT3 9ED Northern Ireland
Contact Name	Rhona Love Manager, QA and Regulatory Affairs
Date of Application	30TH March 2001
Device Name	
Trade Name:	TelePress III Blood Pressure Monitor
Classification Name:	Non-invasive Blood Pressure Monitoring System as per 21 CFR 870.1130

Substantially Equivalent Devices

The Telepress III Blood Pressure Monitor is substantially equivalent to the BP-Tel™ Transtelephonic Blood Pressure Meter (K983717) manufactured by Aerotel Medical systems (1998) Ltd.

Description of the Device

The TelePress III Blood Pressure monitor is a standard A&D UA-779 blood pressure monitor (K993888) that has a communications board added. This communications board links to the Mokdanit interface unit also known as the Home Care Centre (HCC). The HCC supplies power to the TelePress III and passes the measured parameters over the public telephone system to a call centre.

The TelePress III utilises the oscillometric method to detect blood pressure. The fuzzy logic feature of the TelePress III means that it automatically senses the correct pressure to inflate the cuff for the measurements to take place. The cuff is inflated to approximately 30mmHg above the users systolic reading. The cuff is then deflated and the pressure oscillations used to determine the systolic and diastolic pressures and pulse rate.

These readings are automatically sent to the Home Health Centre (HCC), which in turn sends the readings to the Medical Monitoring Centre over the telephone line.

The TelePress III unit is a 130mm x 145mm x 56mm unit weighing approximately 400 grams. It is constructed from high impact ABS plastic, which is designed for use in the home environment.

Intended Use of the Device

The TelePress III Blood Pressure Monitor is intended to detect blood pressure and transmit the measured parameters of pulse rate, systolic and diastolic pressures over the public telephone network to a call centre for recording and monitoring purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2001

Ms. Rhona Love
Meridian Medical Technologies Ltd.
207 Airport Road West
Belfast BT3 9ED
Northern Ireland
GREAT BRITAIN

Re: K011058
Trade Name: TelePress III Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Monitor
Regulatory Class: Class II (two)
Product Code: DXN
Dated: July 23, 2001
Received: July 25, 2001

Dear Ms. Love:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011058

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: MERIDIAN MEDICAL TECHNOLOGIES LTD

510(k) Number (if known):

Device Name: TelePress III Blood Pressure Monitor

Indications For Use:

The TelePress III Blood Pressure Monitor is intended to detect blood pressure, and transmit the measured parameters of pulse rate, systolic and diastolic pressures over the PSTN to a call centre for recording and monitoring purposes..

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Prescription ✓

Division of Cardiovascular & Respiratory Devices
510(k) Number K011058